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10/762,714	01/22/2004	Maxwell Gordon	1360-001	5204

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	**PAPER NUMBER**
1617	
MAIL DATE	**DELIVERY MODE**
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,714	GORDON, MAXWELL	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/30/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I, namely claims 1-17 and 19-20, in the reply filed on 7/31/2007 is acknowledged. Applicant asserts that no reason was set forth which shows that the subject matter of Groups I and II are independent and distinct. Upon further reconsideration, the Examiner agrees with this assertion and withdraws the restriction requirement. Therefore, claims 1-20 are being examined on their merits herein.

Claim Rejections – 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 11, 13 and 15 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of, does not reasonably provide enablement for the prevention of the constipating effect of oxycodone with naloxone. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required

undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

1) The nature of the invention and breadth of the claims: The invention is drawn to solid pharmaceutical dosage forms comprising an opiate, an opiate antagonist and a hydrocolloid which includes an amount of enteric coated opiate antagonist pellets that are effective to prevent opiate induced constipation.

2) The state of the prior art: The start of the art regarding treating opiate induced constipation with naloxone is well known in the art. McNicols et al. (J Pain, Vol. 4, No 5, 2003: p 231-256) review articles in which naloxone was given to patients taking opiates for pain, in which dose-related increases in laxative effects were observed (pages 245-249). However, there is no indication that prevention of constipation occurred.

3) The amount of direction or guidance presented and the presence or absence of working examples: The present specification does not outline examples showing that naloxone prevents oxycodone-induced constipation. It is known in the art, as evidenced by the MiNicols et al. review, that opioid antagonists such as naloxone are

effective treatments for constipation, but there is no indication that naloxone prevents constipation from ever occurring.

4) The quantity of experimentation necessary: In order to determine if naloxone prevents oxycodone induced constipation from ever occurring, one would have to administer naloxone and observe that constipation never happens. As discussed by McNicols et al., naloxone dose-dependently treats constipation in most patients, but does not completely abolish constipation in all patients.

Claim Rejections – 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-11 and 19-20 rejected under 35 U.S.C. 102(e) as being anticipated by Oshlack et al. (US Patent 7,144,587).

Oshlack et al. teach solid dosage forms of compositions comprised of an opiate, an opiate antagonist and a hydrocolloid containing excipient (meeting the limitation of claims 1 and 19; Col. 6, lines 16-20). More specifically the opiates are chosen from

agents such as morphine, codeine and oxycodone (meeting the limitation of claim 2; see Col. 12, lines 34-56 for a more complete list). Antagonists that are useful in the invention include naltrexone and naloxone (meeting the limitation of claim 4; lines 14-15). Dosage forms are taught that include coated beads including the opiate antagonist (meeting the limitation of claim 6; Col. 17, lines 23-61). In regards to the limitation that the amount of the enteric coated opiate antagonist pellets is effective to prevent opiate induced constipation, it would be obvious that because Oshlack et al. teach coated beads, it would necessarily prevent opiate induced constipation. It is taught that gelling agents are included in the dosage forms, which include hydroxypropylmethylcellulose, alginates, xanthan gum, locust bean gum and microcrystalline cellulose (meeting the limitation of claims 7-9 and 20; Col. 7, lines 20-31 and Examples 1-2). The gelling agents impart a gel-like quality to the dosage form if it is tampered with and prevent abuse of the dosage form by minimizing absorption (Col. 7, lines 48-55). It is further taught that when the dosage form is tampered with and exposed to a small amount of a liquid such as water, the dosage form will be unsuitable for injection (meeting the limitation of claim 18; Col. 3, lines 12-16). Diluents for the oral capsule or tablet include lactose (meeting the limitation of Col. 16, lines 48-55). A dosage form comprising oxycodone and xanthan gum is exemplified in Examples 1 and 2 and it is further taught that other suitable agents include locust bean gum (meeting the limitation of claims 10-11). Dosage forms of naloxone are taught that are effective in the invention of Oshlack et al.; therefore, the claim limitation of naloxone in the form of enteric-coated pellets

effective to prevent the constipating effect of oxycodone in claim 10 is met by Oshlack et al.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-15 rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al (U.S. Patent 7,144,587) as applied to claims 1-11 and 19-20 above.

Oshlack et al. teach solid pharmaceutical dosage forms comprised of an opiate, an opiate antagonist and a hydrocolloid.

Oshlack et al. do not have a specific example that includes methadone as the opiate together with naloxone, locust bean gum and xanthan gum as listed in claim 12 or opium powder together with naloxone, locust bean gum and xanthan gum as listed in claim 14.

Oshlack et al. does teach that methadone is an opiate that is useful in the invention (meeting the limitation of claims 12-13; Col. 12, line 46), in addition to the teachings of naloxone and locust bean gum and xanthan gum being in the composition as well. Because opium powder is an opiate, it would be obvious that it would be useful as an opiate in the present invention (meeting the limitation of claims 14-15). Further, Oshlack et al. teaches that the opiate/opioid antagonist formulation together with a

hydrocolloid can be formulated in immediate release formulations or controlled release in any suitable tablet (Col. 17, lines 12-15), and teaches coated beads that can contain the opiate, the opiate antagonist and hydrocolloid. Therefore, it would be obvious that one tablet could contain beads that are controlled and immediate release (meeting the limitation of claim 16-17). Further, because Oshlack et al. teach compositions comprised of the same components, it would be obvious that the composition would be released in the same areas, such as the colon (further addressing claim 16).

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER